

Attorney Docket No. PC25547A

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Status of Claims

Claims 1-5, 7-8, 10-12, 14 and 23 have been amended.

Claims 15-21 have been canceled.

Claims 1-14 and 22-23 are now pending for the Examiner's consideration.

Applicants respectfully request reconsideration and withdrawal of the outstanding objections and rejections, in light of the foregoing amendments and following remarks.

Amendments to the Claims:

Applicants have amended Claim 1 to correct a matter of form and delete the non-elected subject matter; further amended Claim 1 to delete Y=C(O); amended Claims 1-5, 7-8 and 11 to delete the redundant limitations; amended Claims 10, 12 and 14 to correct dependency; amended Claim 12 to correct a matter of form by inserting the missing bracket; and amended Claim 23 into the proper multiple dependent form. No new matter is added.

Solely in order to expedite prosecution of the present application, Applicants have canceled Claims 15-21 without prejudice.

Neither amendment of Claims 1-5, 7-8, 10-12, 14, and 23 nor cancellation of Claims 15-21 constitute any admission regarding patentability of the deleted/cancelled subject matter. Applicants reserve a right to pursue this subject matter in the present or other application(s).

For the reasons that follow, Applicants believe all claims are now in condition for allowance.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 15-23 were rejected under 35 U.S.C. § 112, first paragraph as allegedly lacking enablement for the reasons set forth on pages 2-4 of the Office Action. In light of cancellation of Claims 15-21, the rejection of Claims 15-21 is moot. As to Claims 22-23, Applicants believe that this rejection is improper for the following reasons.

The M.P.E.P. warns that "To avoid confusion during examination, any rejection under 35 U.S.C. 112, first paragraph, based on grounds other than "lack of utility" should be imposed separately from any rejection imposed due to "lack of utility" under 35 U.S.C. 101 and 35 U.S.C. 112, first paragraph." M.P.E.P. §2164.07.

Here, at first, the Office seems to base its rejection on the allegation that the specification does not teach one of ordinary skill in the art to use the composition of Claims 22-23 commensurate in scope with the claims. Applicants assert, however, that a rejection under 35 U.S.C. §112, first paragraph is not justified because in Section IV, entitled "Pharmaceutical Compositions," the application provides sufficient description regarding how to formulate and administer pharmaceutical compositions containing the compounds of the present invention.

Then, the Office appears to reject the claims for lack of utility, citing *In re Buting* 163 USPQ 689 (CCPA 1969), where an asserted use in treating cancer in humans was viewed as

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"incredible." According to the M.P.E.P. §2164.07 I.A, "Office personnel should not impose a 35 U.S.C. 112, first paragraph rejection grounded on a 'lack of utility' basis unless a 35 U.S.C. 101 rejection is proper. In particular, the factual showing needed to impose a rejection under 35 U.S.C. 101 must be provided if a rejection under 35 U.S.C. 112, first paragraph, is to be imposed on "lack of utility" grounds." Thus, if the Office doubts that the composition of Claims 22-23 can be effectively used, a rejection for lack of credible utility should be made first. Here, the Office did not provide any factual showing for lack of a credible utility. Accordingly, the Office fails to establish a proper "lack of utility" rejection under 35 U.S.C. 101 and 35 U.S.C. 112, first paragraph.

In view of the above remarks, Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph be withdrawn.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 1-23 were rejected under 35 U.S.C. § 112, second paragraph, for the reasons set forth on pages 6-9 of the Office Action. By the present amendments, Applicants believe the rejection has been overcome, and respectfully request that the rejection be withdrawn.

Rejection under 35 U.S.C. § 102(e)

Claims 1, 4, 5, 18, 22 and 23 were rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Suto et al. US 2004/0214872. This rejection is inapplicable to the claims because Suto et al. US 2004/0214872 allegedly discloses a compound, wherein R⁸ is -CH₂-CH₂-CH₂-C(O)OH, while the present invention claims compounds, wherein R⁸ is H, -CH₂COOH, phenyl, -CH₃, a C₁₋₆alkyl, or a C₂₋₆alkenyl. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §102(e) over Suto et al. US 2004/0214872 be withdrawn.

Claims 1, 4, 5 and 15-23 were rejected under 35 U.S.C. § 102(e) as anticipated by Ruckle et al. US 2004/0092561. This rejection is inapplicable to the claims as now amended because Ruckle et al. US 2004/0092561 allegedly discloses a compound, wherein Y is C(O), while the present invention claims compounds, wherein Y is C(S). Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 102(e) over Ruckle et al. US 2004/0092561 be withdrawn.

Rejection under 35 U.S.C. § 103

Claims 1-23 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Ruckle et al. US 2004/0092561. Applicants believe the rejection is improper.

Ruckle et al. US 2004/0092561 was published on May 13, 2004. The instant application claims priority to U.S. provisional application No. 60/435,227, filed on December 20, 2002. Thus, Ruckle et al. US 2004/0092561 should not be considered as a §103(a) reference. Applicants respectfully request that the rejection under § 103 over Ruckle et al. US 2004/0092561 be withdrawn.

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Claim Objections

Although the Office Action objects to Claim 21 as being in improper form, Applicants believe that this objection is directed to Claim 23 instead. Applicants have amended Claim 23 into the proper multiple dependent form, and respectfully request that the objection be withdrawn.

Conclusion

Applicants believe all claims are now in condition for allowance. Should there be any issues that have not been addressed to the Examiner's satisfaction, Applicants invite the Examiner to contact the undersigned attorney.

Applicants do not believe any fees are due in connection with this response. If any fees are due in connection with this response, please charge such fees to Deposit Account No. 500329.

Respectfully submitted,

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